

REMARKS

I. Status of Claims

Claims 1-44 are pending in the instant application and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Claims 15-44 have been withdrawn from consideration as being drawn to unelected inventions. Claims 1-14 have been examined. Claims 1, 4, 8, and 14 stand rejected under 35 U.S.C. §102(b) as anticipated by published PCT patent application WO 95/30008 to Tonks et al. Claims 1-14 have been rejected under 35 U.S.C. § 112, second paragraph.

Claims 1 and 9 have been cancelled. Claims 2-6, 8, 10, 12, 13 and 14 have been amended. Claims 45-55 have been added. Please charge additional claim fees in the amount of \$246.00 to Deposit Account No. 50-0246. No new matter has been added. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made."

Additionally, the Patent Office notes that claims 2-3, 5-7 and 9-13 are free of the art. Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Response to the Claim Objections

The Patent Office states that amino acid sequences appearing in the claims of the present patent application do not comply with the rules governing sequence listings. The Patent Office states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the 'Sequence Listing' in accordance with 37 CFR 1.821(c) (MPEP 2422), reference must be made to the sequence by use of the sequence identifier, preceded by 'SEQ ID NO:' in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." Official Action, page 2.

Applicants have amended claims 3 and 10 to include the identifier "SEQ ID NO: 1." Additionally, applicants have amended the specification to include the identifiers "SEQ ID NO: 1" and "SEQ ID NO: 2" where appropriate. Support for these

amendments is found throughout the specification as filed. Applicants submit that the claims and the specification are in compliance with the rules governing sequence listings (i.e. 37 CFR 1.821 *et seq.*).

III. Response to the Rejection of the Claims Under 35 U.S.C. §102(b)

The Patent Office has rejected claims 1, 4, 8 and 14 under 35 U.S.C. § 102(b) based on PCT International Publication No. WO 95/30008 by Tonks et al. (hereinafter "Tonks et al."). The Patent Office's basis for this rejection is set forth in detail at pages 2-3 of the Official Action.

Summarily, it is the Patent Office's position that Tonks et al. discloses "antibodies to the human DEP-1 protein which appears to be the same protein [as ECRTP/DEP-1] and has functional activities that are drawn to receptor tyrosine phosphatases." Official Action, pages 2-3. The Patent Office further states: "[t]he antibodies are inherently used in a pharmaceutically acceptable buffer to study *in vivo* binding and/or signal transduction activities which are some of the uses described in Tonks et al." Official Action, page 3. Applicants respectfully traverse the rejection and submit the following comments.

Applicants have cancelled claim 1, rendering the rejection of this claim moot. Applicants have also amended claims 4, 8 and 14 to depend from claim 2, which has been amended to independent form. Applicants note that the Patent Office has declared claim 2 free of the art.

In view of the amendment of claims 4, 8 and 14 to depend from claim 2, applicants submit that claims 4, 8 and 14 are also free of the art. Applicants respectfully request that the rejection of claims 4, 8 and 14 under 35 U.S.C. §102(b) based on Tonks et al. be withdrawn. Applicants further submit that claims 4, 8 and 14 are in condition for allowance and respectfully solicit the same.

IV. Response to Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-14 have been rejected under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Official Action, page 3.

Applicants note that the Court of Appeals for the Federal Circuit has repeatedly stated that absolute precision is not required to adequately define the metes and bounds of the claims of a patent application. "Section 112, ¶2, requires only reasonable precision in delineating the bounds of the claimed invention." U.S. v. Electronics, Inc., 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046 (1989) (citation omitted) (emphasis added). The Court of Appeals for the Federal Circuit has also clarified the test for the definiteness of a claim: "[t]he test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." Miles Laboratories, Inc. v. Shandon, Inc., 27 U.S.P.Q.2d 1123, 1126 (Fed Cir. 1993), cert. denied 510 U.S. 1100 (1994) (citations omitted).

A. The Term "Preferentially"

The Patent Office first contends that claims 1-4 and 8-11 are indefinite because the metes and bounds of the term "preferentially" are not clear. Applicants respectfully traverse the rejection and submit the following comments.

Applicants note that the metes and bounds of a patent claim are to be gauged in terms of how one of ordinary skill in the art would interpret the language of the claim. Applicants submit that one of ordinary skill in the art would readily understand the meaning of the term "preferentially." The term "preferentially" is a term commonly and regularly employed by those of ordinary skill in the art when discussing the epitope recognition profile of an antibody. In the context of the present invention, one of ordinary skill in the art would recognize that the term "preferentially" refers to an antibody that when exposed to a heterogeneous mixture of compounds, the antibody will bind to a compound comprising given epitope. Applicants submit that further definition of the term is not needed or required. Additionally, claim 1 has been cancelled, making the rejection of this claim moot.

Claim 13 has also been amended for clarification. Support for this amendment can be found throughout the subject application as filed, including in original claim 7.

Claim 13 now recites that the humanized antibody is a monoclonal antibody produced by a hybridoma cell line having ATCC accession number HB12570.

Applicants submit that in light of the above remarks, claims 2-4 and 8-14 are definite and respectfully request that the rejection of claims 2-4 and 8-14 under 35 U.S.C. § 112, second paragraph be withdrawn. Applicants further submit that claims 2-4 and 8-14 are in condition for allowance and respectfully solicit the same.

B. The Term "Analog Sequence"

Next, the Patent Office contends claims 3 and 10 are ambiguous in the recitation of the term "analog sequence." Applicants respectfully traverse the rejection and submit the following comments.

Applicants direct attention to page 36, lines 10-21 of the specification as filed.

~~This paragraph clearly defines the meaning of the term "analog" as it is used in the specification and the claims as follows:~~

The term "analog" includes any polypeptide having an amino acid residue sequence substantially identical to a sequence of the natural ligand of the ECRTP/DEP-1 in which one or more residues have been conservatively substituted with a functionally similar residue and which displays the ECRTP/DEP-1 modulator activity as described herein. Examples of conservative substitutions include the substitution of one non-polar (hydrophobic) residue such as isoleucine, valine, leucine or methionine for another; the substitution of one polar (hydrophilic) residue for another such as between arginine and lysine, between glutamine and asparagine, between glycine and serine; the substitution of one basic residue such as lysine, arginine or histidine for another; or the substitution of one acidic residue, such as aspartic acid or glutamic acid for another.

The paragraphs following the definition of the term "analog" (e.g., page 36, line 22 through page 38, line 22) further clarify the meaning and usage of the term. The definition of "analog" remains the same when it is used as a descriptor, as in the term "analog sequence."

Applicants submit that the specification makes the meaning of the term "analog sequence" clear and thus, the term is not ambiguous. Applicants therefore respectfully request that the rejection of claims 3 and 10 under 35 U.S.C. § 112, second paragraph, be withdrawn. Applicants further submit that claims 3 and 10 are in condition for allowance and respectfully solicit the same.

C. The Term "Immunoreaction Characteristics"

Finally, the Patent Office states claims 6 and 12 are indefinite because the metes and bounds of the term "immunoreaction characteristics" are not clear. Applicants respectfully traverse the rejection and submit the following comments.

Although applicants submit that the meaning of the term "immunoreaction characteristics" is well known to those of ordinary skill in the art, claims 6 and 12 have been amended by way of a non-limiting amendment to replace the term "immunoreaction characteristics" with the term "specificity" in order to clarify this point. Applicants note that the terms "immunoreaction characteristics" and "specificity" are widely recognized as equivalent terms. Additionally, the use of the term "specificity" to describe antibody binding is well established. Support for this amendment is found throughout the specification as filed, notably on page 46, lines 11-15.

Applicants submit that in light of the amendments, claims 6 and 12 are definite and respectfully request that the rejection of claims 6 and 12 under 35 U.S.C. § 112, second paragraph, be withdrawn. Applicants further submit that claims 6 and 12 are in condition for allowance and respectfully solicit the same.

V. New Claims 45-55

New claims 45 and 46 have been added. Each of these claims recite that the antibody has activity in the modulation of angiogenesis. Support for this amendment can be found throughout the specification as filed, including at page 28, lines 4-9; page 29, lines 21-22; page 34, lines 13-18; and page 41, lines 20-24.

New claims 47-52 have been added. New claims 47-52 include the recitations that the antibody fragment is selected from the group consisting of an Fab fragment, an Fab' fragment, an F(ab')2 fragment and an F(v) fragment; and that the F(v) fragment is an scFv fragment. Support for this amendment can be found throughout the specification as filed, including at page 43, lines 4-9; and at page 50, line 1.

New claims 53 and 54 have been added. These claims recite that the antibody binds an eight amino acid epitope having the sequence QSRDTEVL (SEQ

ID NO: 1). Support for this amendment can be found throughout the specification as filed, including in original claims 3 and 10.

New claim 55 has been added. Claim 55 recites an antibody having the specificity of an antibody produced by the hybridoma cell line having ATCC accession number HB12750. Support for this claim is found throughout the specification as filed, notably on page 42, lines 12-17.

Applicants submit that new claims 45-55 are free of the art and are in condition for allowance. Applicants therefore respectfully solicit the same.

#### CONCLUSIONS

In light of the above amendments and remarks, applicants submit that the subject patent application is in condition for allowance and courteously solicit a Notice of Allowance.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

#### Deposit Account

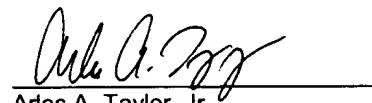
The Commissioner is hereby authorized to charge any deficiencies of payment associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS & WILSON, P.A.

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